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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,674	11/21/2001	Gordon L. Woods	2404-105	1175

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,674	WOODS, GORDON L.	
	Examiner	Art Unit	
	Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *1-19,26-60,62 and 63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-25 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on November 20, 2003, PROSECUTION IS HEREBY REOPENED. A new ground of rejection set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Currently, claims 1-63 are pending in this application.

It is noted in the previous Office Action dated May 21, 2002, claims 1-19, 26-60, and 62-63 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. A complete reply to the Office Action must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 20-25 and 61 are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-25 and 61 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for a method for increasing or maintaining the plasma or serum levels of cadmium in a human if levels of cadmium in the body are lower than the normal range of cadmium in said human body disclosed in the specification, does not reasonably provide enablement for decreasing or removing cadmium from a human if levels of cadmium in the body are higher than the normal range of cadmium in said human body.

The instant claims are drawn to a method of **balancing** the concentration of cadmium in body fluids an tissue of a human. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The instant invention pertains to a method of **balancing** the concentration of cadmium in body fluids a tissue of a human, i.e., increasing and/or decreasing the level of cadmium in a human.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or lack thereof in the art: The skilled artisan would view that, balancing, encompassing both increasing and decreasing or removing, the concentration of cadmium in body fluids an tissue of a human by administering a physiologically acceptable cadmium salt, is highly unpredictable since the skilled artisan would not understand how the same cadmium compound could increase and decrease the concentration of cadmium in body fluids a tissue of a human.

The amount of direction or guidance presented and the presence or absence of working examples: In the instant case, the results in the specification at pages 45-47 show that the cadmium levels rise to normal in a human suffering cadmium deficiency after administering cadmium to said human. However, **no** working examples are presented in the specification showing how to decrease the concentration of cadmium or remove cadmium in body fluids an tissue of a human, by using the same cadmium.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad claimed method for any balancing the concentration of cadmium in body fluids a tissue of a human recited in the instant claims.

Therefore, in view of the *Wands* factors, e.g., the amount of direction or guidance provided, absence of working examples, and the predictability of the art discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-22, 24-25 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations, "balance", 'said unbalanced levels" and "sufficient to balance said cadmium concentration" renders these claims indefinite. Hence, one of ordinary skill in the art could not interpret the metes and bounds of the patent protection desired as to the recitations "balance", 'said unbalanced levels" and "sufficient to balance said cadmium concentration". Thus, these claims are indefinite as to how much cadmium concentration to be administered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 23-24 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobson et al. (BRITISH JOURNAL OF NUTRITION, (1977 Jan) 37 (1) 107-26, PTO-892).

Jacobson et al. discloses that twenty trace elements such as silver, arsenic, gold, bromine, **cadmium (Cd)**, cobalt, chromium, caesium, copper, iron, mercury, lanthanum, molybdenum, rubidium, antimony, scandium, selenium, samarium, tungsten and zinc, in salts, as nutrition, are administered to a human (patients) by parenteral or intravenous, in order to correcting the negative balances (or deficiency) of these trace elements such as cadmium in the said human body (see abstract, Table 1 and "Experimental" at page 108, "Subjects": human subjects tested, at page 110, the 3rd paragraph at page 111). Jacobson et al. also discloses the known amounts of Cd to be administered daily, 50-60 μg (equal to 0.05-0.06 mg) or 5-68 μg (within the instantly claimed range, see page 121 the last paragraph to the third paragraph of page 122). Jacobson et al. also points out that "The administration of trace elements is recommended in long-term total parenteral nutrition". See abstract in particular. Jacobson et al. discloses the method for determining the corresponding balance values of these trace elements in a human body by analyses for trace elements made with the aid of an ion-exchange technique based on neutron activation, and combined with subsequent gamma spectrometry (see abstract and Table 5).

Thus, Jacobson et al. anticipates Claims 20, 23-24 and 61.

Claims 20 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakatos et al. (US 4225592, PTO-892).

Lakatos et al. teaches that trace elements such as cadmium (Cd), copper, iron, and zinc, are well known to be administered to a human as nutrition (see col.9 lines 25-

46). It is noted that the teachings regarding the administration of these trace elements in Lakatos et al. have been cited from several prior art references (see col.9 lines 21-46).

Thus, Lakatos et al. anticipates Claims 20 and 61.

Claims 20 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Cini et al. (US 5130298, PTO-892).

Cini et al. discloses that zinc, cadmium (Cd), cobalt, calcium, magnium, nickel, tin, potassium, and lithium in the pharmaceutical acceptable cation salt or the complex salt, are administered to a human. See abstract, col.3 line 64 to col.4 lines 7-9, and col.5). Cini's disclosure inherently treating a human suffering from cadmium deficiency, as claimed herein since Cini's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389.

Thus, Jacobson et al. anticipates Claims 20 and 61.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobson et al. or Lakatos et al.

The same disclosure of Jacobson et al. or Lakatos et al. have been discussed in the 102(b) rejections set forth above.

The prior art does not expressly disclose the particular unbalance levels of cadmium in a human and the particular cadmium salt to be administered.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine the unbalanced levels of cadmium in a human and to determine the particular pharmaceutically acceptable cadmium salt to be administered in order to increase the concentration of cadmium in body fluids and tissues of a human suffering from unbalanced levels of cadmium in his body fluid and tissues and for correcting a cadmium deficiency in a human suffering therefrom.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the unbalanced levels of cadmium in a human and to optimize the daily dose of cadmium to be administered in a methods of increasing the concentration of cadmium in body fluids and tissues of a human suffering from unbalanced levels of cadmium in his body fluid and tissues and for correcting a cadmium deficiency in a human suffering therefrom, since the method of determining the levels of trace elements in a human body is known according to Jacobson. The determination of the particular pharmaceutical acceptable cadmium salt to be administered, is considered well within conventional skills in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is 571.272.0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on 571.272.0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
February 19, 2004

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

2/22/04